REMARKS

Claim Rejection - 35 U.S.C. § 112

The rejection of claims 22- 48, under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement, was maintained for reasons of record. This rejection is respectfully traversed.

This is a Supplemental Amendment further to the Amendment filed July 8, 2008, in which Applicants provided evidence that the counterpart UK application has been granted. In this Supplemental Amendment, Applicants provide evidence that the counterpart EPO application has also been granted as European Patent No. 1 490 103 B1 on June 11, 2008, *without* any rejection for lack of enabling disclosure during the prosecution of the counterpart EPO application. A copy of European Patent No. 1 490 103 B1 (EP '103 patent) is attached herewith. Claim 1 of EP '103 patent reads:

> 1. Use of mycobacterium w, or constituents of mycobacterium w for the preparation of a pharmaceutical composition for use in the treatment, management or prevention of obstructive lung disease.

On the other hand, claim 22 of the pending application recites:

> 22. A method of treating, managing or preventing obstructive lung disease comprising:
>
> administering to a patient a pharmaceutical composition comprising an effective amount of (a) Mycobacterium w or (b) a constituent of Mycobacterium w.

It is quite clear from the plain reading of claim 1 of EP '103 patent and claim 22 of the pending application that the scope of claim 1 of EP '103 patent is the same or substantially the same as that of claim 22 of the pending application.

With respect to the enablement standard of the EPO, Article 83 provides:

> The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The EPO has confirmed that its enablement requirements are not satisfied where the specification places an undue burden on a person skilled in the art (Boards of Appeal of the European Patent Office T 0994/95 – 3.3.4 (February 18 1999)).

On the other hand, the adequacy of the specification in the United States is governed by 35 USC Section 112, first paragraph, which provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The Federal Circuit has clarified that the specification must sufficiently describe the claimed invention so that it conveys that the inventors had possession of the claimed invention *and* describe the claimed invention so that a person skilled in the art is enabled to make and use the invention (*University of Rochester v G D Searle & Co, Inc*, 358 F3d 916, 921 (Fed Cir 2004)).

In short, the enablement standards of the EPO and the USPTO are the same or substantially the same as the enablement requirements under both standards are not satisfied where the specification places an undue burden on a person skilled in the art to practice the invention. While Applicants understand that the USPTO and the EPO are independent patent granting authorities, Applicants respectfully submit that the USPTO should at least consider the evidence that the counterpart EPO application has been granted as being ***persuasive*** for overcoming the enablement rejection in the US application as the EPO patent law also has a similar enablement standard ("[t]he European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art" without "undue burden on a person skilled in the art" (see above)) as that under the US patent law.

Applicants respectfully submit that the EPO has reviewed the counterpart EPO application and granted claims of the same or substantially the same scope as those pending in the US application. Applicants believe that the evidence in the form of the grant of the counterpart EPO application with claims of same or substantially the same scope as those in the present application in addition to the evidence presented along with the Amendment of July 8, 2008, should be more than sufficient grounds for the withdrawal of the enablement rejection.

Applicants believe the pending application is in condition for allowance.

Dated: July 9, 2008

Respectfully submitted,

By /Raj S. Dave/
Raj S. Dave
Registration No.: 42,465
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant